Boston Scientific

JETSTREAM™ PVCN100 Console

Operator's Manual

TABLE OF CONTENTS

JETSTREAM™ PVCN100 Console

Operator's Manual

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

This device is only for use with the JETSTREAM™ Catheter and Control Pod. Before using this device, read the information contained within this manual and the current revision of the Directions for Use applicable to the Catheter and Control Pod that will be connected to this device for use.

DEVICE DESCRIPTION

The PVCN100 Console along with the JETSTREAM Catheter and Control Pod products (packaged separately) form a rotational atherectomy system which provides a differentially cutting tip for use in debulking and treating vascular disease in the peripheral vasculature. The System includes multiple distal ports located at the catheter tip, which are designed to provide independent infusion and aspiration functions for the active removal of fluid, excised tissue and thrombus from the peripheral treatment site.

Contents

One (1) JETSTREAM PVCN100 Console

One (1) Power Cord

One (1) Operator's Manual

Figure 1. PVCN100 Console and IV Stand

PVCN100 Console

A reusable PVCN100 Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The PVCN100 Console mounts on a standard IV stand and remains outside the sterile field during the procedure.

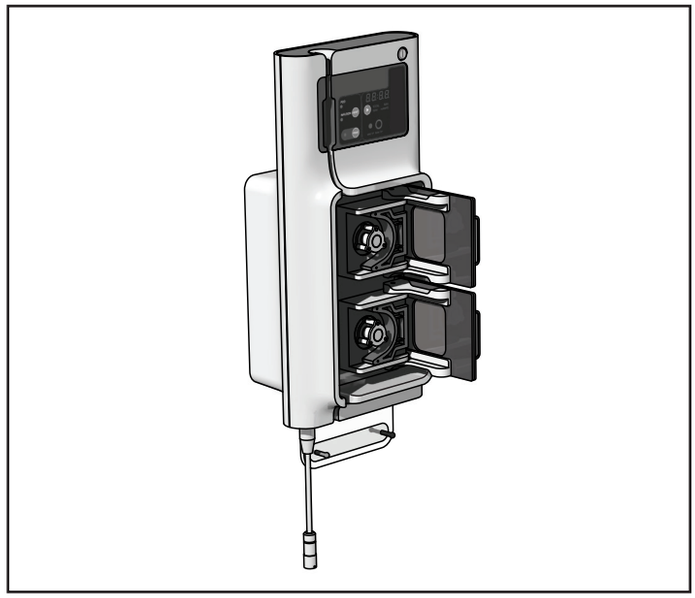


Figure 2. PVCN100 Console

Catheter and Control Pod

Note: The Directions for Use packaged with the Catheter and Control Pod may still reference the PVCN100 Console Catheter Tip Speed Display. All Catheters will function as intended whether connected to a PVCN100 Console still equipped with a speed display or one without a speed display.

BATON

The Baton loads easily into the PVCN100 Console. It is used to place the aspiration and infusion tubing onto the pump rollers for quick setup.

CONTROL POD

The Control Pod houses the detachable Activation Handle, which provides a user interface.

ACTIVATION HANDLE

The Activation Handle has keypad controls for device operation.

CATHETER

The Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities.

GARD

The GARD maintains guidewire position and prevents the guidewire from rotating during the procedure.

FLUSH PORT

The Flush Port is a self-sealing membrane used when removing air in the infusion line.

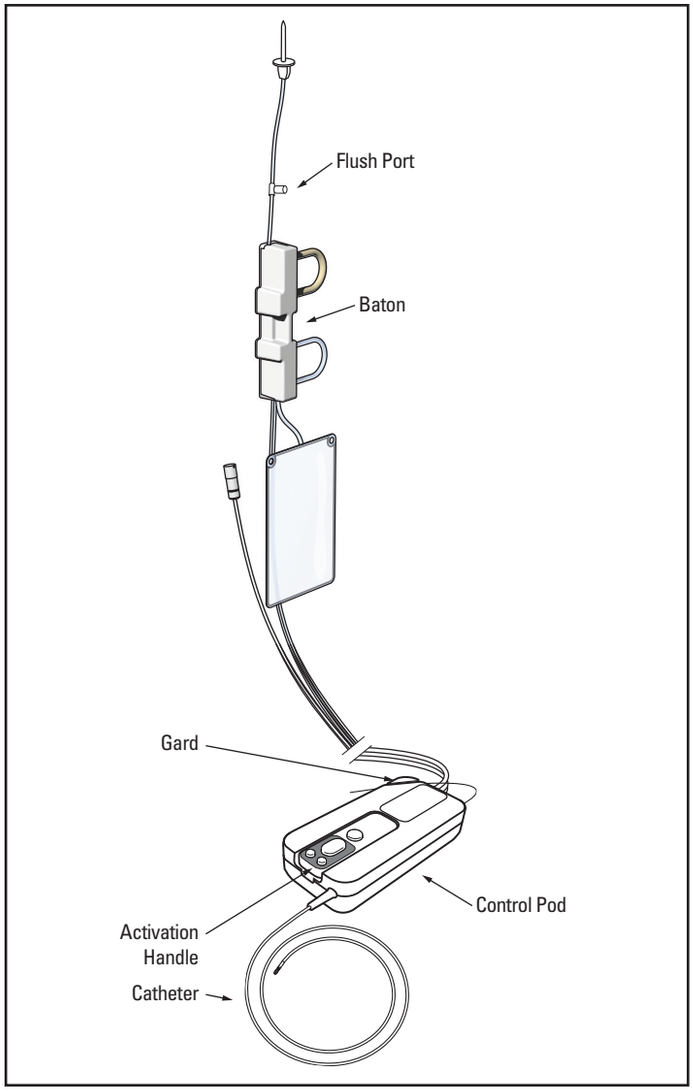


Figure 3. Catheter and Control Pod

INTENDED USE/INDICATIONS FOR USE

The PVCN100 Console is designed for use only with the JETSTREAM™ Catheter and Control Pod.

See the current revision of the applicable Catheter and Control Pod Directions for Use for further information.

CONTRAINDICATIONS

None known.

WARNINGS AND PRECAUTIONS

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- The System should only be used by physicians trained in percutaneous peripheral interventional procedures and who have had specific instruction in the use of the System.
- Do not open either pump door during operation of the System. Doing so could result in loss of aspiration and/or infusion and will halt device activation.
- Ensure the PVCN100 Console display is visible during the entire procedure.
- Observe normal safety practices associated with electrical/electronic medical equipment.
- Avoid excessive coiling or bending of the power cables during storage.
- Store the PVCN100 Console using appropriate care to prevent accidental damage.
- Do not place objects on the PVCN100 Console.
- Do not immerse the PVCN100 Console in liquids.

HOW SUPPLIED

This product is supplied non-sterile and is intended for multiple use.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Operating Environment

Temperature: 10 °C to 40 °C (50 °F to 104 °F)

Relative Humidity: 30% to 75% (noncondensing)

Atmospheric Pressure: 70 kPa to 106 kPa

Transport Environment

Temperature: -29 °C to 60 °C (-20 °F to 140 °F)

Relative Humidity: 30% to 85% (noncondensing)

Atmospheric Pressure: 50 kPa to 106 kPa

Storage Environment

Temperature: -29 °C to 60 °C (-20 °F to 140 °F)

Relative Humidity: 30% to 85% (noncondensing)

Atmospheric Pressure: 50 kPa to 106 kPa

DEVICE INSTALLATION

Assembly and Installation

1. Carefully unpack the PVCN100 Console and power cord.
2. Attach the PVCN100 Console to the specified IV stand using the integrated, adjustable clamp.
   - The PVCN100 Console is designed to be mounted on a standard IV stand that meets the following minimum requirements of 24 in (61 cm) base and 5 wheels.
   - Compliance testing was performed with a Brewer IV stand, PN 11360. Any other IV stand may not satisfy stability requirements.
3. Do not mount the PVCN100 Console higher than 59 inches (1.5 m) from the ground (measuring from the top of the console). The stability of the stand could be compromised.
4. Insert the power cord into the receptacle located on the rear of the PVCN100 Console.

Connection and Setup

Note: Refer to the Catheter and Control Pod Directions for Use for complete system setup instructions.

1. Plug the PVCN100 Console's power supply cord into an electrical outlet. To turn the main power on, press the Main Power ON/OFF button located on the upper right front corner of the PVCN100 Console.

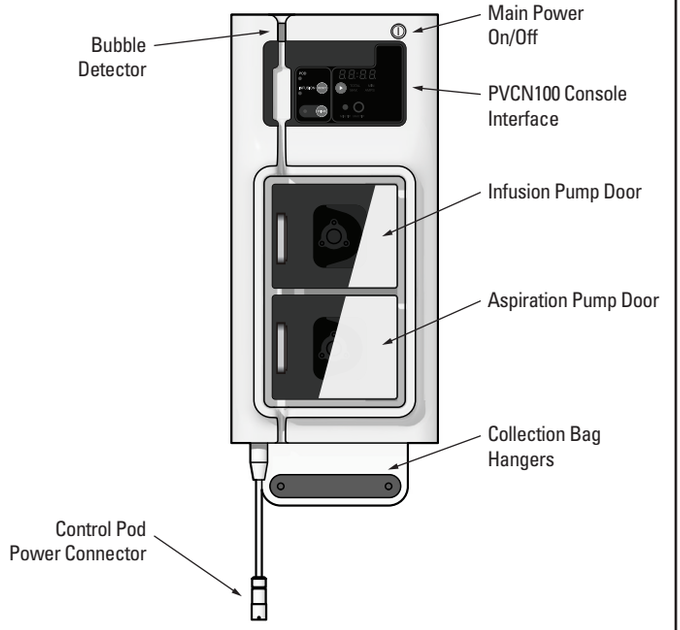
   CAUTION: Grounding reliability can only be achieved when the power cord is connected to a "Hospital Only" or "Hospital Grade" receptacle.

2. Connect the electrical cable from the Catheter and Control Pod to the Control Pod Power Connector on the PVCN100 Console.
3. Open the pump doors and insert the Baton such that the tubing is positioned over the pump rollers. Press the tubing onto the center of the pump rollers. The Collection Bag should be hanging down if the Baton is oriented properly.
4. Close the pump doors and then attach the Collection Bag to the pegs located below the pumps.

   Caution: Take care to avoid being pinched when closing the aspiration and infusion pump doors.

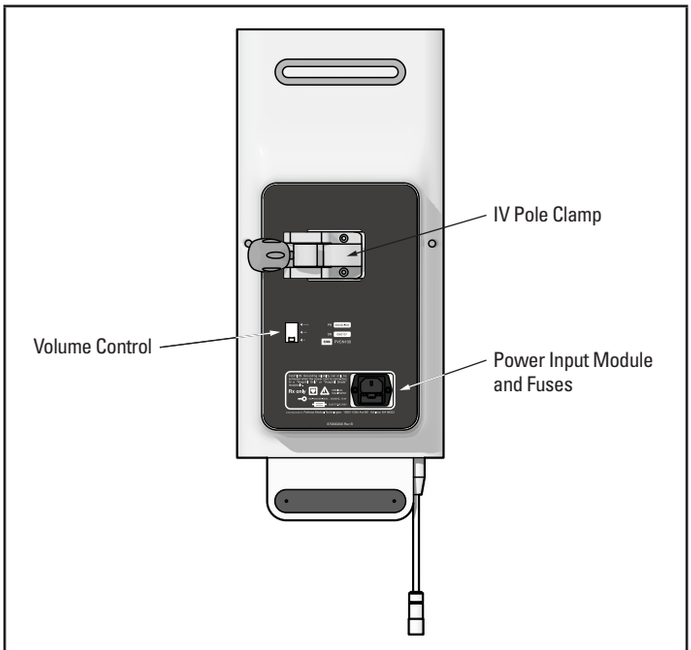
5. Insert the infusion tubing's bag spike into a bag of normal saline solution and hang the bag from the hook on the IV stand.
6. Insert the infusion tubing into the Bubble Detector.

CONTROLS AND INDICATORS



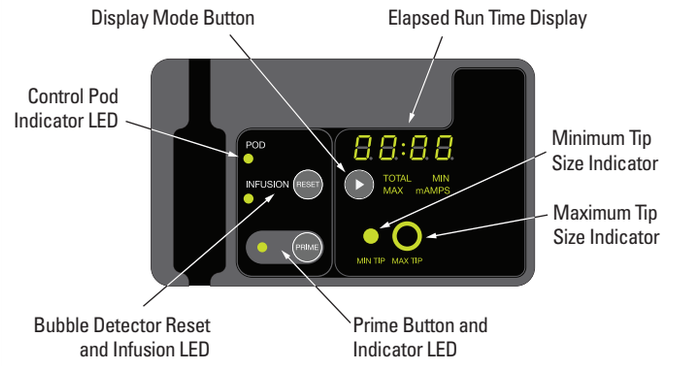
Main Power On/Off	Press to turn the PVCN100 Console ON and OFF
Bubble Detector	Detects air bubbles in the tubing
PVCN100 Console Interface	Provides feedback and monitoring during the procedure
Infusion Pump Door	Closes pump bed around infusion tubing
Aspiration Pump Door	Closes pump bed around aspiration tubing
Collection Bag Hangers	Pegs to hang collection bag
Control Pod Power Connector	Provides power to Control Pod and Activation Handle

Figure 4: Front Panel



IV Pole Clamp	Clamp for standard 5-wheel 24 in (61 cm) base IV pole
Power Input Module and Fuses	Provides power to the PVCN100 Console and houses electrical fuses
Volume Control	Controls audible volume of warning indication beeps

Figure 5. Back Panel



Control Pod Indicator LED POD	Indicates a functional Control Pod is connected to the PVCN100 Console
Bubble Detector Reset and Infusion LED RESET	Resets the Bubble Detector; Infusion LED turns green when priming is complete
Prime Button and Indicator LED PRIME	Initiates and pauses the priming process: LED flashes orange to prompt priming and turns off when complete
Display Mode Button	Toggles the information on the display between: total run time, min run time, max run time, and mAmps
Elasped Run Time Display 00:00	The timer displays the elapsed run time for the Catheter and Control Pod
Maximum Tip Size Indicator	Indicates that the Catheter Tip is at Maximum Size
Minimum Tip Size Indicator	Indicates that the Catheter Tip is at Minimum Size

Figure 6. User Interface

USING THE JETSTREAM™ SYSTEM

System Operation

1. Refer to the applicable Catheter and Control Pod Directions for Use for operating the PVCN100 Console and Catheter and Control Pod as a system.

Note: If the System goes through a power recycle due to a power interruption, the Catheter and Control Pod will need to be re-primed. When power returns, remove the infusion line from the Bubble Detector, unclamp the guidewire from the GARD, reinsert the infusion line into the Bubble Detector, and press the prime button.

Note: If the System shuts down during the procedure and power cannot be restored, remove the catheter from the patient while maintaining guidewire position. If the guidewire position cannot be maintained, remove the guidewire with the catheter.

2. When the procedure is complete turn the main power off by pressing the Main Power ON/OFF button located on the upper right front corner of the PVCN100 Console.

JETSTREAM™ PVCN100 CONSOLE SYMBOL TRANSLATION KEY

REF	Catalog Number
	Follow Instructions for Use
	Contents
EC REP	EU Authorized Representative
	Legal Manufacturer
LOT	Lot
	Recyclable Package
AUS	Australian Sponsor Address
ARG	Argentina Local Contact
BRA	Brazil Local Contact
TUR	Turkey Local Contact
	Do not use if package is damaged.
	Humidity Limitation(s)
	Type CF Applied Part
	Separate Collection
	Fuse
	Alternating Current
T	Time Lag
	Temperature Limitation(s)
	Atmospheric Pressure Limitation
	Date of Manufacture
SN	Serial Number
NON STERILE	Non-Sterile
	Non-Ionizing Electromagnetic Radiation
ETL CLASSIFIED Intertek 3161809	Medical Electrical Equipment ANSI/AAMI ES 60601-1 CAN/CSA C22.2 No. 60601-1

MAINTENANCE, TROUBLESHOOTING AND SERVICE

General Maintenance

The PVCN100 Console requires no routine maintenance or calibration, and cannot be serviced by the user or facility biomedical engineer.

WARNING: User modification of the PVCN100 Console is not allowed.

If a defect is evident or suspected, please contact Boston Scientific to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

Fuse Replacement

There are two 2.0A, 250 V fuses located in the power input module on the rear of the PVCN100 Console. Replace blown fuse with an equivalent UL/CSA rated fuse: 5x20 mm Cartridge Fuse, T2.0A, slow-blow 250 V (Examples: Littelfuse P/N 0218002.HXP and Digikey P/N F2420-ND). Remove the fuse by first disconnecting the power cord, depressing the small tab on the fuse holder, and then pulling the fuse holder straight out from the rear of the connector.

If a fuse blows a second time, contact Boston Scientific to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

Cleaning

To clean the PVCN100 Console, turn it off and wipe it down with any of the following disinfecting solutions: Cidex, 10% bleach solution, or alcohol.

- Do not immerse the PVCN100 Console in disinfecting solutions, water, or other solvents.
- Do not autoclave or sterilize the PVCN100 Console

Troubleshooting

PVCN100 Console Does Not Power Up

1. Verify that the power cord is properly connected and plugged into an electrical outlet.
2. Verify that the PVCN100 Console's Main Power ON/OFF button is turned on.
3. Verify that the facility electrical outlet is functioning.
4. Check for blown fuses (See Fuse Replacement).

Note: If the PVCN100 Console does not power up after performing Steps 1 – 4, contact Boston Scientific to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

Display Codes

If a code appears on the PVCN100 Console display, take the action specified below:

00:00	When the "00:00" is displayed, the PVCN100 Console is ready for a Control Pod to be connected.
tubE	If the "tubE" message shows on the display at power up, remove the fluid-filled tubing from the Bubble Detector and then proceed with setup. If the "tubE" message does not clear when the Bubble Detector is empty, discontinue use of the device and turn off the PVCN100 Console. Contact Boston Scientific to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.
door	The "door" message will flash when either Pump Door is not completely closed. In the event that a Pump Door becomes ajar during use, the "door" message will appear on the display and PVCN100 Console operation will be stopped. To resume operation, reclose the Pump Door.
bubL	If "bubL" appears on the display the Bubble Detector has detected a bubble. Clear the bubble and press the Bubble Detector Reset button. The Flush Port on the infusion tubing line may be used to clear a bubble from the infusion line. Insert a sterile syringe with a 16 gauge or higher needle tip into the Flush Port and extract the bubble.
Pod	If "Pod" appears on the display after plugging in the electrical cable, the PVCN100 Console has detected a problem with the Control Pod. Replace the Catheter and Control Pod with a new one.
grd1	If "grd1" appears on the display after plugging in the electrical cable, the PVCN100 Console has detected a possible problem with the GARD. Remove the guidewire from the GARD and the message should disappear. If the message persists, replace the Catheter and Control Pod with a new one.
grd2	"grd2" will appear on the display if activation is attempted (by depressing the Activation switch) without a guidewire clamped in the GARD. Clamp the guidewire in the GARD. If the message persists, replace the Catheter and Control Pod with a new one.
F001-F009	If the system detects a PVCN100 Console fault during power up, it will display an "F" followed by a three digit number. For example, "F002." If a fault message appears on the display during power up, discontinue use of the device and turn off the PVCN100 Console. Contact Boston Scientific to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.
Err1-Err9	If the PVCN100 Console detects a fault during operation, it will display an "Err" followed by a one digit number. For example, "Err2." If a fault message appears on the display during operation, discontinue use of the device and turn off the PVCN100 Console. Contact Boston Scientific to obtain a Return Goods Authorization (RGA) Number and to make arrangements to return the product.

Display Errors

In the event that the PVCN100 Console loses its display function or does not operate properly, discontinue use of the device and turn off the PVCN100 Console. Contact Boston Scientific to obtain a Return Goods Authorization (RGA) Number and make arrangements to return the product.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.

SPECIFICATIONS

Classification

The PVCN100 Console is part of a Class I device system and is used with the JETSTREAM™ Catheter and Control Pod, which is a Type CF applied part.

Electrical Safety

The JETSTREAM™ PVCN100 Console is compliant with ANSI/AAMI ES 60601-1, CAN/CSA C22.2 No. 60601-1, IEC 60601-1 and EN 60601-1.

Electrical Specifications

Input Characteristics	100 to 120 VAC, 50/60 Hz, 70 VA 200-240 VAC, 50/60 Hz, 70VA
Output Characteristics	Maximum output voltage: 22.00 ± .90 VDC Minimum output current: 1.10 Amperes + .055 Amperes

Environmental Specifications

Operating conditions	Controlled, catheterization laboratory environment Temperature: 10 °C to 40 °C (50 °F to 104 °F) Relative Humidity: 30% to 75% (noncondensing) Atmospheric Pressure: 70 kPa to 106 kPa
Shipping and Storage conditions	Temperature: -29 °C to 60 °C (-20 °F to 140 °F) Relative humidity: 30% to 85% (noncondensing) Atmospheric Pressure: 50 kPa to 106 kPa
Protection against ingress of liquid	IPX 0

ELECTROMAGNETIC COMPATIBILITY

Medical Electrical Equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the documents accompanying the equipment. Portable and mobile radio frequency (RF) communications equipment can affect Medical Electrical Equipment. Use of a power cord other than the cord supplied may result in increased emissions or decreased immunity of the System.

Table 1. Guidance and manufacturer's declaration – electromagnetic emissions
The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions (CISPR 11)	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class A	The System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations flicker/ emissions (IEC 61000-3-3)	Complies	

WARNING: The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

Table 2. Guidance and manufacturer's declaration – electromagnetic immunity

The System is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst (IEC 61000-4-4)	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	If the system shuts down due to power mains interruption, user should discontinue device activiation and refer to the DFU/ Operating manual for further information.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
			Recommended Separation Distance
Conducted RF (IEC 61000-4-6)	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.77\sqrt{P}$ $d = 1.77\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2.33\sqrt{P}$ 80 MHz to 2.5 MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 U_T is the a.c. mains voltage prior to application of the test level.
NOTE 2 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 3. Recommended separation distances between portable and mobile RF communications equipment and the System

The System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)[2]		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz[1] $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

BRA **Brazil Local Contact**

Para informações de contato da Boston Scientific do Brasil Ltda, por favor, acesse o link www.bostonscientific.com/bra

TUR **Turkey Local Contact**

Boston Scientific Tıp Gereçleri Ltd. Şti.
Altunizade Mah. Ord. Prof. Fahrettin Kerim Gökay Cad. 45/1
Üsküdar 34662, İstanbul
Tel +90 216 544 47 00
Faks +90 216 544 47 01

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

Do not use if package is damaged.

Recyclable Package

CE 0086

2015-04

91024736-01